PSJ3 Exhibit 523

From: Hauser, Ronna < rhauser@ncpanet.org>
Sent: Wednesday, March 19, 2014 7:42 PM

To: Ducca, Anita

Subject: RE: Hydrocodone Combination Products Proposed Rule Follow-up - Response

Requested by March 17

Yes that is a good idea to have Cindy join our calls – she is a great advocate for patients.

From: Ducca, Anita [mailto:aducca@hdmanet.org] Sent: Wednesday, March 19, 2014 2:40 PM

To: Hauser, Ronna

Subject: RE: Hydrocodone Combination Products Proposed Rule Follow-up - Response Requested by March 17

Hi, Ronna, I wanted to let you know that the only other person from the PCF that said they would join a working group on hydrocodone comments was Cindy Steinberg from RNC. I believe this is one of the groups that supports Long Term Care Facilities, but thought I'd ask if you knew anything more.

I was thinking that maybe rather than starting a separate workgroup, she might just want to join the informal calls with the pharmacy groups — you know NACDS, NCPA and APhA such as the one we're arranging for this Friday? Do you know Cindy? Do you have any thoughts on this?

Thanks, Anita

From: Hauser, Ronna [mailto:rhauser@ncpanet.org]

Sent: Monday, March 17, 2014 11:27 PM

To: Ducca, Anita; Ritter, Pam

Subject: RE: Hydrocodone Combination Products Proposed Rule Follow-up - Response Requested by March 17

Hi Anita and Pam – I'm happy to participate on a PCF workgroup – I'm also looking forward to our call this Friday. Thanks, Ronna

From: Ducca, Anita [mailto:aducca@hdmanet.org]

Sent: Thursday, March 13, 2014 3:12 PM

To: Adriane Burke; Aimee Welch Champion; Alan McEmber; Alec Stone; Alex Bardakh; Alexander Kraus; Alice Mead; Aliza Tomlinson; Amy Goldstein; Andrea Best; Ducca, Anita; Anita Roach; Annelies Hall; Barbara Marcanti; Bennett, Pamela (Gov't Affairs); Bill Franco; Brent Fisk; Brian Munroe; Bruce Colligen; Caitlin McCormick; Ha. Carolyn; Catherine Ferguson; Catherine Frank; Catherine Underwood; Chrissy Kopple; Cindy Steinberg; Claudia Campbell; Craig Burton; Crystal Muilenburg; Dan Cohen; Dan Ignaszewski; Daniel Raymond; Dara Mann; David Duhrkoop; David E. Joranson; David Swankin; David Woodmansee; Donna Kalauokalani; Dr. Alfred Anderson; Elizabeth (Libby) Terry; Elora Gupta; Erensen, Jennifer; Erin Morton; Felix Lara; Gaby Geise; Gail Amalia B. Katz; George Bilyk; Greg Hicks; Gregory Terman; Haddox, Dr. J. David; Henrietta Ukwu; James Lavery; Janet Favero Chambers; Janet McUlsky; Jeremy Scott; Jerry Hall; Cosgrove, Jewelyn; Jillanne Schulte; Jillian Manley; Jim Broatch; Jody Green; Jonathan Jagoda; Jonathan Keyserling; Jordan Wildermuth; Joy Buck; Judi Lund Person; June Dahl PhD; Justine Coffey; Kaelan Hollon; Kathleen Strauser; Kathy Sapp; Kevin L. Zacharoff; Kevin Nicholson; Keysha Brooks-Coley; Khyati Roberts; Kirsten Sloan; Freitas, Kristen; Kristen Hedstrom; Kristin Recchiuti; Lauryl Jackson; Lee Claassen; Lenore Duensing; Linda Kitlinski; Lisa Pearlstein; Lisa Robin; Loyce Pace Bass; Mark Fleury; Marsha Stanton; Marta Sokolowska; Matt Gunderman; Michael Barnes; Michael Ghobrial; Micke Brown; Mike Heffernan; Myra Christopher; Natacha Pires; Nicole Kelly; Nina DeLorenzo; Patrick Coyne; Paul Arnstein; Paul Gileno; Paul Scott O'Neill; Paul, Ilisa Halpern; Peggy Tighe; Penney Cowan; Peter Reinecke; Peter VanPelt; Philip Saigh Jr.; Rebecca Kirch; Robert Falb; Robert Radie; Robert Saner; Robert Twillman; Ron Kuntz; Hauser, Ronna;

Case: 1:17-md-02804-DAP Doc #: 2364-78 Filed: 08/14/19 3 of 4. PageID #: 385543

Rosemary Garza; Rosen, Burt; Sally Welsh; Sara Rosta; Sharon Brigner; Sharon Stancliff; Sherrie Dornberger; Steve LaPierre; Sue Thau; Susan Rogers; Susan Stone; Tiffany McCaslin; Tiller, Kimberley; Timothy Byrne; Tina Tockarshewsky; Tom O'Donnell; Wade Delk; Whitney Englander; William Gray; Windy Y. Carson-Smith Cc: Caitlin Reicks; Elise Bailey; Gina Angelo; Nancy Beltramo; Tony Kudner; Michangelo.Kittrell@cancer.org
Subject: Hydrocodone Combination Products Proposed Rule Follow-up - Response Requested by March 17

Dear Pain Care Forum Members:

During today's discussion of DEA's <u>proposed</u> rule to reschedule hydrocodone-combination products, there were three requests: 1) find out if anyone is interested in forming a subgroup to discuss the rule further, 2) forward the back-up documentation found on DEA's rulemaking docket and 3) provide the quotes from DEA's documents mentioned on the call.

First, if you wish to participate in a Subgroup/Workgroup to discuss the proposal further, please indicate your interest below and respond to my assistant Pam Ritter at Pritter@hdmanet.org, preferably by Monday, March 17. Unfortunately, I cannot serve as coordinator for such a Workgroup, but I agreed to collect names of those interested and ask if there are any volunteers for this function. Thus, please also indicate if you would be willing to serve as the Workgroup's Coordinator. (If someone else can take the lead, I'll be able to participate.)

1.	Do you wish to participate in a Workgroup to discuss and consult with each other on the DEA proposal to upschedule Hydrocodone Combination Products? (Please indicate your preferred e-mail address for correspondence on this topic if it's different from the one we have for PCF e-mails.) YES NO
2.	Would you be available to serve as the Workgroup Coordinator for facilitating/managing conference calls, meetings, etc.? YES NO

Second, the information available on DEA's rulemaking docket (http://www.regulations.gov/#!docketDetail;D=DEA-2014-0005) is attached to this e-mail.

- the 44 page referral letter from HHS to DEA,
- the 110 page Eight Factor Analysis, and
- the 39 page Economic Impact Analysis.

Third, the specific quotes are as follows:

The DEA estimates that only the physical security requirements will have material economic impact and such impacts will be limited to manufacturers, exporters, and distributors.

[79 Fed. Reg. at page 11045 Col. 1 (February 27, 2014)]

This rule will not *require* a patient visit each time a prescription is issued for HCPs when it is issued for a legitimate medical purpose... Therefore, the DEA estimates that this rule will not require an increase in the number of patient-doctor visits: and therefore, any cost associated with prescription requirements is nominal.

[ECONOMIC IMPACT ANALYSIS of Schedules of Controlled Substances: Rescheduling Hydrocodone Combination Products from Schedule III to Schedule II. (Bottom of P. 23 - February 2014.) Note-- the word *require* is italicized in DEA's document.]

Although the following wasn't mentioned on the call, it may also be of interest.

The DEA's assessment of economic impact...indicates that the proposed rule... will not have a significant economic impact on a substantial number of small entities.

[79 Fed. Reg. at page 11045 Col. 2 (February 27, 2014)]

If you have any questions, my contact information is below. Thank you.

Regards,

Anita

Anita T. Ducca Vice President, Regulatory Affairs Healthcare Distribution Management Association (HDMA) 901 North Glebe Rd., Suite 1000 Arlington, VA 22203 (703) 885-0240 Fax: (703) 812-5282

e-mail: aducca@hdmanet.org www.HealthcareDistribution.org